REMARKS

Claims 1, 4-11, 13-15, 33-41, and 43-45 are pending. Claims 1 and 33 have been amended to specify that the control capture reagent can react with analyte-binding particles, but does not interact with the analyte of interest or with the analyte-binding agent on the analyte-binding particles. Support for this amendment is found, for example, at p. 14, lines14-16; p. 21, lines 19-23).

Applicants' Invention

Applicants invention is drawn to methods for quantitatively measuring the amount of an analyte of interest in a fluid sample. The methods involve providing a membrane having an application point, a contact region comprising analyte-binding particles, a sample capture zone, and a control capture zone, where the contact region is between the application point and the sample capture zone, and the sample capture region is between the contact region and the control capture zone. In the assays, a fluid allows transport components of the assay by capillary action through the contact region, to and through the sample capture zone and subsequently to and through the control capture zone. The methods utilize an internal control to compensate for variability in specific binding of assay components during the assay (intrinsic assay variability).

The amount of binding of analytes to particles, as well as the location of particles in relation to positions on the solid phase, is in flux because of the flow of fluid in the membrane. Variations in the structure of the solid phase reactants, such as porosity of the solid phase reactants, as well as variations in the viscosity of the fluid sample and other factors, can contribute to variability in specific binding of components of the assays (intrinsic assay variability). Intrinsic assay variability differs from sample concentration variability, in which the amount of analyte in the test sample can vary. The methods of the invention compensate for intrinsic assay variability, by taking into consideration the variations that result from the dynamic nature of the assays, and thereby allow more accurate determination of the amounts of analytes of interest in solutions. Furthermore, the use of a control capture reagent that can react with analyte-binding particles but does not interact with the analyte of interest or with the analyte-binding agent on the analyte-binding particles allows selection of components of the internal control that have characteristics similar to those of the analyte and the analyte binding agent (e.g.,

binding affinity, susceptibility to temperature, and aging degradation of binding). In addition, the concentration of the components of the internal control can be adjusted independently of the concentration of the other components of the assay.

Rejection of Claims under 35 U.S.C. 102(b)

The Examiner rejected the claims as being anticipated by Kuo (EP 0 895 084 A2).

In order for a reference to anticipate a claim, each and every element at set forth in the claim must be found, either expressly or inherently described, in the reference (see, e.g., M.P.E.P. §2131). The following element of the claims is neither expressly or inherently described by Kuo: Kuo does not teach the use of the control capture reagent that can react with analyte-binding particles but does not interact with the analyte of interest or with the analyte-binding agent on the analyte-binding particles. Kuo teaches that the capture agent that is immobilized in zone 3 is an agent "which contains means for capturing the analyte/labeled specific binding partner complex which is not bound in the second region" (see, e.g., p. 3 lines 2-3 of Kuo). The definition of the material bound (analyte/labeled specific binding partner complex) is set forth (see p. 2, line 58) as a labeled binding agent which reacts with antigen to form said complex. Kuo also teaches that an immobilized antibody against the labeled binding partner can be used as a capture means (p. 4, lines 9-11). Both of these capture agents (a means that captures the complex of analyte and labeled specific binding partner, and an antibody against the labeled binding partner) are different from the agent used in the current invention, namely, an agent which does not bind to the analyte of interest or to the analyte-binding agent (e.g., which binds to the labeled particles alone). In view of these considerations, Kuo does not teach each and every aspect of the claimed invention. Therefore, the claims are not anticipated by the teachings of Kuo.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call Elizabeth W. Mata at (915) 845-3558 (Mountain Time Zone). If Elizabeth W. Mata cannot be reached, the Examiner is invited to call David E. Brook at (978) 341-0036..

Respectfully submitted,

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